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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,091	11/25/2003	Jose Remacle	4044.001	7897
7590 11/03/2004				
PENDORF & CUTLIFF 5111 Memorial Highway Tampa, FL 33634-7356			EXAMINER WESSENDORF, TERESA D	
			ART UNIT 1639	PAPER NUMBER

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/723,091	Applicant(s) REMACLE ET AL.	
	Examiner T. D. Wessendorf	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Status of Claims

Claims 1-19 are pending and under examination.

Specification

The disclosure is objected to because of the following informalities: grammatical error at page 11 [00051], line 3.

Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Non sequitur for "the reagents" in claim 7.

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B. Claim 9 is indefinite as to the recited "the proteins to be identified and/or quantified." The base claim 1 does not recite for identification and/or quantification step.

C. Non-sequitur for "the loading solution" in claim 10. The used of inconsistent terminologies provide for confusion. For example, the base claim recites spotting solution. It is suggested that applicants used terms consistently in the claims to avoid any confusion.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "amorphous gas" recited in claim 14.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-9, 12-13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by MacBeath et al (US 2002/0102617).

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MacBeath discloses at [0006] a method for microarraying and/or immobilizing proteins on a solid support and identifying proteins with desired properties. The proteins are arrayed in such a manner as to preserve the function of the proteins or regain their functionality once arrayed on the solid support. One protein may be arrayed, or many different proteins may be arrayed using this method. The surface of the solid support may be arrayed resulting in discrete spots with attached protein, or the entire surface or a portion of the surface of the solid support may be evenly coated with a protein. MacBeath provides arrays of proteins on a solid support. The proteins are arrayed on the solid support so that one spot containing a particular protein is spatially segregated from other spots on the solid support. Preferably, the spots of protein are separated by such a distance as to prevent contamination of one spot with another spot. The proteins arrayed on the support may be one type of protein or many different types of proteins. Preferably, the identity of the protein can be determined by its position in the array. The proteins to be arrayed are provided in a buffered aqueous solution containing a humectant (e.g., glycerol, polyethylene glycol) to prevent evaporation of the nanodroplets. The proteins should remain hydrated throughout the preparation, storage, and assaying of the array to prevent denaturation of

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the protein. The proteins are then contacted with the solid support facilitating attachment through the chemically active sites on the support. MacBeath provides a method of identifying proteins with desired properties. These properties may include a catalytic activity, an ability to bind another protein, an ability to bind a nucleic acid or small molecule, a substrate for phosphorylation, etc. An array of functional proteins is contacted with a biological macromolecule or small molecule of interest, and binding or a chemical reaction is detected in order to identify proteins with the desired property. At [0015] a ligand is defined as any chemical compound, polynucleotide, peptide, protein, lipid, carbohydrate, small molecule, natural product, polymer, etc. that has a binding affinity for a target (e.g., a protein, carbohydrate, lipid, peptide, macromolecules, biological macromolecules, oligonucleotide, polynucleotide). Preferably, the target is a protein. To fabricate protein microarrays, a high precision, contact-printing robot or split pin arrayer is used to deliver nanoliter-scale volumes of protein samples to the slides, yielding spots approximately 1600 spots per square centimeter. Humectants or polymers (e.g., polyethylene glycol, glycerin, maltitol, polydextrose, sorbitol, cetyl alcohol, fatty alcohols, propylene glycol) other than glycerol may be used to prevent evaporation. As would be

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appreciated by one of skill in this art, it is important that the proteins remain hydrated throughout this and subsequent steps to prevent denaturation and/or loss of functionality. The slides were rinsed four times with 95% ethanol and centrifuged as above to yield BSA-NHS slides. The slides were stored in a desiccator under vacuum at room temperature for up to two months without noticeable loss of activity [0077].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over MacBeath in view of Lazar et al (USP 6,686,151).

MacBeath is discussed above. MacBeath does not disclose a microarray in the form of a kit. Lazar discloses a kit. Lazar discloses in the abstract a method and kit to detect and measure biological molecules that is simple to use, highly specific, sensitive, and accurate for screening a plurality of biological

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molecules. The kit may be used to screen samples for large number of targets (col. 6, lines 18-21). Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the microarray of MacBeath into a kit as taught by Lazar. One would have been motivated to form a kit for the advantages taught by Lazar. Also, because of the kits known commercial viability.

MacBeath is discussed, supra. MacBeath does not disclose that polyol solution is between 1 and 5% or as a D-enantiomer or that the capture proteins have at least 70% activity after 6 months of storage. Lauks discloses at [0151], page 15 that sorbitol can be added in 20 % by weight. See further[0152]-[0157]. Gu discloses at col. 48, lines 10-20 D-enantiomers of peptides are more resistant to proteolytic attack. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use 1-5% polyol depending upon the polyol used, which determination is within the ordinary skill in the art. Lauks and MacBeath disclose the use of specific amounts for a specific polyol. It would be within the ordinary skill to adjust such amount to achieve the desired humectant effect. Furthermore, to use a D-enantiomer in the method of MacBeath would have been obvious as taught by Gu. The advantage in the use of D over its L-form as disclosed by Gu

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would provide the motivation to one having ordinary skill in the art at the time of the invention. Moreover, it would have been obvious to one having ordinary skill in the art to add anti-bacterial components to prevent degradation or denaturation of the proteins.

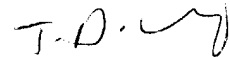
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

November 1, 2004